WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB347 trade name]*

Isoniazid 50 mg dispersible tablets

[TB347 trade name] manufactured at Micro Labs Limited, Hosur, Tamil Nadu, India, was included in the WHO list of prequalified medicinal products for the prevention and treatment of tuberculosis on 16 March 2020.

[TB347 trade name] is currently indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to *Mycobacterium tuberculosis*, including in regimens for drug-resistant tuberculosis. It is also indicated as monotherapy or with other medicines for the prevention of tuberculosis in persons at risks. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient of [TB347 trade name] is isoniazid.

The efficacy and safety of isoniazid are well established based on extensive clinical experience in treatment and prevention of tuberculosis.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of isoniazid for treatment and prevention of tuberculosis, the team of assessors advised that [TB347 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB347 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB347 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 March 2020	listed
Pharmaceutical quality	5 March 2020	MR
Bioequivalence	10 March 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	23 November 2018	MR
FPP	10 April 2019	MR
GCP/GLP (re-)inspection	15 December 2017	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.